75th OREGON LEGISLATIVE ASSEMBLY - 2009 Regular Session **MEASURE: SB 316 A**
STAFF MEASURE SUMMARY **CARRIER: Sen. Devlin**
Senate Committee on Health Care & Veterans Affairs

REVENUE: No revenue impact
FISCAL: Fiscal statement issued

Action:		Do Pass as Amended and Be Printed Engrossed
Vote:		5 - 0 - 0
	Yeas:	Bates, Kruse, Morrisette, Morse, Monnes Anderson
	Nays:	0
	Exc.:	0
Prepared By:		Robert Shook, Administrator
Meeting Dates:		1/29, 4/7

WHAT THE MEASURE DOES: Requires health benefit plans to provide coverage of routine costs of care in qualifying clinical trials (subject to co-pay and other cost-sharing requirements), and limits liability of insurers for adverse effects of clinical trial, and pays participating providers at a different rate than the non-participating providers.

ISSUES DISCUSSED:

- Definition of routine cost of care
- Reimbursement rate for participating providers vs. non-participating providers
- Difference between "enrolling' in clinical trial, and "participating" in clinical trial
- Qualifying clinical trials

EFFECT OF COMMITTEE AMENDMENT: Modifies routine costs to exclude items and services; (1) required solely for the provision of the investigational drug, device or services; (2) required solely for the clinically appropriate monitoring of the investigational drug, device or service; and (3) required solely for the prevention, diagnosis or treatment of complications arising from the provision of the investigational drug, device or service. Removes the requirement that the health plan must reimburse health care providers who do not participate in the plan at the same rate as the plan pays participating providers for the same service not delivered in a clinical trial, taking into account copayments, coinsurance or deductibles.

BACKGROUND: Clinical trials are considered to be biomedical or health-related research studies in human beings that follow a pre-defined protocol. Participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical research. All clinical trials have guidelines about who can participate, based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions, all of which are important in determining if a person is qualified for the study.

A qualifying clinical trial is defined as a clinical trial funded by the National Institutes of Health, Centers for Disease Control and Prevention, Centers of Medicare and Medicaid Services, Department of Veterans' Affairs, US Department of Defense, or US Food and Drug Administration.

SB 316 would require health benefit plans to provide coverage for routine costs of care of patients enrolled in and participating in qualifying clinical trials. Currently, insurers are contractually obligated to pay for routine costs of care; however, some health plans don't cover these costs once a patient joins a clinical trial. This bill also defines routine costs of care and clinical trials, and requires health plans to cover these routine costs of care for patients. An insurer that provides coverage is not liable for any adverse effects of the clinical trial.